

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/
FENFLURAMINE/DEXFENFLURAMINE)) MDL NO. 1203
PRODUCTS LIABILITY LITIGATION)

THIS DOCUMENT RELATES TO:)
SHEILA BROWN, et al.) CIVIL ACTION NO. 99-20593
v.)
AMERICAN HOME PRODUCTS) 2:16 MD 1203
CORPORATION)

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.

8474

Bartle, C.J.

May 18, 2010

Diane E. McGath ("Ms. McGath" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").²

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1
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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In May, 2003, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Antoine M. Adem, M.D. Based on an echocardiogram dated December 26, 2002, Dr. Adem attested in Part II of Ms. McGath's Green Form that claimant suffered from moderate mitral regurgitation and a reduced ejection fraction in the range of 50% to 60%.³ Based on

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describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

3. Dr. Adem also attested that claimant suffered from New York Heart Association Functional Class I symptoms. This condition, however, is not at issue in this claim.

such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$538,973.⁴

In the report of claimant's echocardiogram, the reviewing cardiologist, Ronald G. Woodson, M.D., stated that claimant had "[m]oderate mitral valve insufficiency." Dr. Woodson, however, did not specify a percentage as to claimant's level of mitral regurgitation. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In August, 2005, the Trust forwarded the claim for review by Lawrence S. Mendelson, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Mendelson concluded that there was no reasonable medical basis for Dr. Adem's finding that claimant had moderate mitral regurgitation because claimant's echocardiogram demonstrated no mitral regurgitation. In support of this conclusion, Dr. Mendelson explained that:

There is no mitral regurgitation. There is no systolic flow originating from the mitral valve into the left atrium in any view on this tape. I do not know how the attesting

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4. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's finding of a reduced ejection fraction, which is one of the complicating factors needed to qualify for a Level II claim, the only issue is the level of claimant's mitral regurgitation.

physician concluded there was any mitral regurgitation, much less moderate [mitral regurgitation].

Based on the auditing cardiologist's finding that claimant had no mitral regurgitation, the Trust issued a post-audit determination denying Ms. McGath's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁵ In contest, claimant argued that under the reasonable medical basis standard, the attesting physician's conclusions should be accepted unless they are "extreme or excessive." Claimant also asserted that the auditing cardiologist's determination lacked a reasonable medical basis.⁶ Claimant further contended that

5. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. McGath's claim.

6. In support of this assertion, claimant relied on the report of her December 26, 2002 echocardiogram and also submitted reports for echocardiograms performed on April 2, 1999 and May 3, 2004. The April 2, 1999 echocardiogram report stated that claimant had "[m]ild to moderate mitral valve insufficiency." The May 3, 2004 echocardiogram report stated that claimant had "[m]ild mitral regurgitation." Claimant also asserted that an April 1, 1999 medical record, which reflected that Dr. Woodson found a "2-3/6 systolic ejection murmur," and Dr. Mendelson's statement that claimant's left atrium was "borderline enlarged" established that there was no reasonable medical basis for the auditing cardiologist's conclusion that claimant did not have any mitral regurgitation. Claimant, however, did not provide any expert submission or cite any medical literature in support of this argument.

"[q]uantifying the level of regurgitation shown on an echocardiogram is inherently subjective."⁷ Finally, claimant suggested that the Trust was not properly applying the reasonable medical basis standard established in the Settlement Agreement and that the auditing cardiologist simply substituted his own opinion for that of the attesting physician.⁸

The Trust then issued a final post-audit determination again denying Ms. McGath's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. McGath's claim should be paid. On February 28, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 6028 (Feb. 28, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting

7. In support of this argument, claimant submitted excerpts of depositions of five (5) physicians from other proceedings. None of the testimony submitted by claimant, however, addressed Ms. McGath's echocardiogram.

8. Claimant also asserted that the Trust should ensure that its auditing cardiologists do not have any "biases" against claimants. As there is no evidence that the auditing cardiologist had a "bias," this issue is irrelevant for resolution of this claim. Similarly, claimant referenced, without any substantive discussion, a number of filings in MDL 1203. As claimant has not attempted to establish how those filings entitle her to Matrix Benefits, they are not pertinent to the disposition of this show cause claim.

documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on June 2, 2006, and claimant submitted a sur-reply on June 23, 2006. The Show Cause Record is now before the court for final determination. See Audit Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. McGath reasserts the arguments that she made in contest. In addition, claimant argues that there is a reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation because two cardiologists opined that she had moderate mitral regurgitation. Finally, claimant suggests that it is not uncommon for two cardiologists to review the same echocardiogram and to find different levels of regurgitation. According to claimant,

"[n]either diagnosis is correct or incorrect; both fall within the realm of having 'a reasonable medical basis.'"

In response, the Trust disputes claimant's characterization of the reasonable medical basis standard. Moreover, the Trust argues that claimant failed to rebut Dr. Mendelson's specific findings. The Trust further asserts that "an audible murmur does not and cannot conclusively establish the degree of mitral regurgitation or the presence or degree of any valvular heart disease."

In her sur-reply, claimant reasserts her argument that she should prevail because "echocardiogram interpretation is highly subjective." Claimant also notes that the Trust failed to acknowledge that the attesting physician was merely concurring with Dr. Woodson's original conclusion that claimant had moderate mitral regurgitation.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, and of crucial importance, claimant does not adequately contest Dr. Mendelson's finding that Ms. McGath's December 26, 2002 echocardiogram did not demonstrate the presence of any mitral regurgitation. Despite the opportunity in the contest period to present additional evidence in support of her claim, Ms. McGath rests only on Dr. Adem's check-the-box diagnosis on her Green Form and the reports of several echocardiograms.⁹ Claimant never

9. We also reject claimant's argument that these additional
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identified any particular error in Dr. Mendelson's conclusions. Instead, claimant asserts that the auditing cardiologist "is simply wrong." Mere disagreement with the auditing cardiologist without identifying and substantiating any specific errors by the auditing cardiologist is insufficient to meet a claimant's burden of proof.¹⁰ On this basis alone, claimant has failed to meet her burden of demonstrating that there is a reasonable medical basis for her claim.

We also disagree with claimant's characterization of the reasonable medical basis standard. We are required to apply the standards delineated in the Settlement Agreement and the Audit Rules. The context of these two documents leads us to interpret the reasonable medical basis standard as more stringent than claimant contends, and one that must be applied on a case-by-case basis. Here, Dr. Mendelson determined in audit, and Ms. McGath does not adequately dispute, that there is no

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echocardiogram reports establish a reasonable medical basis for her claim as neither echocardiogram report addresses Dr. Mendelson's specific finding with regard to claimant's Green Form echocardiogram. In particular, the April 2, 1999 echocardiogram report simply states that claimant had "[m]ild to moderate mitral valve insufficiency," without any quantification of the percentage of regurgitation. In addition, the May 3, 2004 echocardiogram report states that claimant had only "[m]ild mitral regurgitation."

10. In addition, claimant's assertion that there is a reasonable medical basis for her claim because three cardiologists concluded that she had at least mild mitral regurgitation is misplaced. Under the Settlement Agreement, claimant must establish that she has the requisite level of mitral regurgitation. As discussed herein, claimant has not met this burden.

reasonable medical basis for the attesting physician's representation that claimant had moderate mitral regurgitation. According to Dr. Mendelson, "[t]here is no systolic flow originating from the mitral valve into the left atrium in any view on this tape."¹¹ Contrary to claimant's argument, Dr. Mendelson properly applied the reasonable medical basis standard established under the Settlement Agreement.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. McGath's claim for Matrix Benefits.

11. Similarly, we disagree with claimant that the conflict between the attesting physician and the auditing cardiologist is due to the "subjective nature of echocardiography." Nor has Dr. Mendelson merely substituted his opinion for that of the attesting physician. Instead, Dr. Mendelson specifically found that there was no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation. Neither claimant nor claimant's attesting physician, however, adequately refuted or responded to this determination.